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Pest Management Regulatory Agency *Information Note*

17 September 2004

Proposed Phaseout of Citronella-Based Personal Insect Repellents

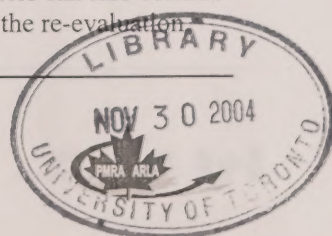
Canada's Pest Management Regulatory Agency (PMRA), the federal regulatory body for the registration and re-evaluation of pesticides in Canada, has completed its review of available information of citronella-based personal insect repellents applied to the skin. As a result of the re-evaluation, the PMRA is recommending that citronella-based insect repellents that are applied to the skin be phased out, unless further data are provided to address data uncertainties and endpoints of concern. This re-evaluation does not cover other uses of citronella, such as in candles, as a food additive or as a scented agent in

Citronella was re-evaluated as part of the PMRA's current program to re-assess all pesticides registered prior to 1995 to determine if they meet modern health and environmental risk management standards. As part of its re-evaluation process, the PMRA seeks input on its proposed decision. This consultation exercise is part of the usual process where the Agency seeks input from stakeholders and the general public before making a final regulatory decision. The consultation period also allows companies to commit to providing the missing data required during the re-evaluation.

Health concerns of re-evaluation and proposed decision on citronella-based insect repellents

Citronella repellents are often applied directly to the skin, over a relatively large area of the body, leading to high exposures. Because citronella-based products repel insects for only about 30 minutes, repeated applications can lead to even greater exposures. While no significant health risks were identified with the use of these products, the companies marketing them have not provided adequate safety data to support their continued registration. The limited safety data available for citronella-based insect repellents has brought a number of concerns to light. Citronella oil may contain methyleugenol, which has been shown to be carcinogenic in laboratory studies. In addition, tests in laboratory animals indicate a potential for reproductive and developmental toxicity as well as fetal sensitivity at high dose levels. As a result, the PMRA has concluded that the use of citronella-based personal insect repellents continues to be a concern and is proposing to phase out this use.

The scientific rationale for the proposed decision are included in PACR2004-36, *Review of Citronella Oil and Related Active Compounds for Use as Personal Insect Repellent*, available on the PMRA's website. As part of the PMRA's re-evaluation process, interested parties have until 17 November 2004 to provide further information or comments to influence the finalization of the re-evaluation decision by the PMRA. Manufacturers can also commit to providing the data required to address the uncertainties identified during the re-evaluation.



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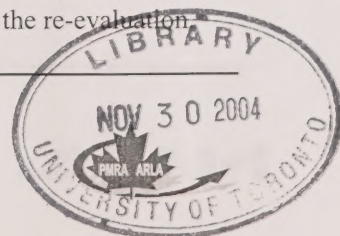
Health Canada's Pest Management Regulatory Agency (PMRA), the federal regulatory body responsible for the registration and re-evaluation of pesticides in Canada, has completed its re-evaluation of available information of citronella-based personal insect repellents applied directly to the skin. As a result of the re-evaluation, the PMRA is recommending that citronella-based insect repellents that are applied to the skin be phased out, unless further data are provided to address data uncertainties and endpoints of concern. This re-evaluation does not apply to other uses of citronella, such as in candles, as a food additive or as a scenting agent in cosmetics.

Citronella was re-evaluated as part of the PMRA's current program to re-assess all pesticides registered prior to 1995 to determine if they meet modern health and environmental risk assessment standards. As part of its re-evaluation process, the PMRA seeks input on its proposed decision. This consultation exercise is part of the usual process where the Agency seeks comments from stakeholders and the general public before making a final regulatory decision. The consultation period also allows companies to commit to providing the missing data identified during the re-evaluation.

Overview of re-evaluation and proposed decision on citronella-based insect repellents

Insect repellents are often applied directly to the skin, over a relatively large area of the body, which leads to high exposures. Because citronella-based products repel insects for approximately 30 minutes, repeated applications can lead to even greater exposures. While no imminent health risks were identified with the use of these products, the companies marketing them have not provided adequate safety data to support their continued registration. The limited data available for citronella-based insect repellents has brought a number of concerns to light. Natural citronella oil may contain methyleugenol, which has been shown to be carcinogenic in animal studies. In addition, tests in laboratory animals indicate a potential for reproductive and developmental toxicity as well as fetal sensitivity at high dose levels. As a result, the PMRA was unable to conclude that the use of citronella-based personal insect repellents continues to be acceptable and is proposing to phase out this use.

Details of the scientific rationale for the proposed decision are included in PACR2004-36, *Re-evaluation of Citronella Oil and Related Active Compounds for Use as Personal Insect Repellents*, available on the PMRA's website. As part of the PMRA's re-evaluation process, interested parties have until 17 November 2004 to provide further information or comments prior to finalization of the re-evaluation decision by the PMRA. Manufacturers can also commit to generating the data required to address the uncertainties identified during the re-evaluation.



Citronella-based personal insect repellents will remain on the market during this consultation period. They will also remain on the market until any information received during the consultation has been assessed and a final decision has been reached. If no additional information is provided during the comment period to warrant a change in the current PMRA proposal, a phase-out schedule will be announced at the time the final decision is communicated.

How insect repellents are regulated

All pest control products, including personal insect repellents, are regulated in Canada under the *Pest Control Products Act*. Before a product is registered for use, it must undergo a comprehensive and rigorous scientific assessment to ensure the product does not pose unacceptable risks to human health or the environment and to assess its efficacy to ensure that the lowest effective rate is used. If the assessment does not indicate that a product can be used safely, it is not registered for use in Canada. The same approach is taken during the re-evaluation of registered pesticides.

Assessing risks of natural and synthetic compounds

The PMRA makes no distinction between naturally occurring chemicals and synthetic chemicals when assessing their risks. The risk any chemical poses to your health is a function of its intrinsic hazard (toxicity) and your exposure to it, regardless if it is natural or synthetic.

All chemicals proposed for pesticide use must meet the same “proof-of-safety” standard. In addition, it is the responsibility of those wanting to market a pesticide of any sort to provide proof of safety according to stringent standards.

A natural source of a chemical does not equate to safety. Many powerful toxins are naturally occurring chemicals derived from plants, animals or minerals.

Using personal insect repellents safely

If Canadians choose to use personal insect repellents, they should select a product that meets their needs and use the product according to label directions. The label directions reflect the results of the risk assessment and specify how the product can be used safely. It is important to read the label because different repellents contain different concentrations of the active ingredient, offer different protection times and specify how often the product can be reapplied per age group.



Need more information?

Visit the following links on the PMRA's website to read more about the topics discussed in this document.

Re-evaluation of Citronella Oil and Related Active Compounds for Use as Personal Insect Repellents (PACR2004-36)

<http://www.pmra-arla.gc.ca/francais/pdf/pacr/pacr2004-36-f.pdf>

Safety Tips on Using Personal Insect Repellents

<http://www.pmra-arla.gc.ca/english/consum/insectrepellents-e.html>

Fact Sheet on The Regulation of Pesticides in Canada

http://www.pmra-arla.gc.ca/english/pdf/fact/fs_pestreg-e.pdf

or for more details on the PMRA and pesticide regulation in html format

<http://www.pmra-arla.gc.ca/english/aboutpmra/about-e.html>


Children's Health Priorities within the Pest Management Regulatory Agency (SPN2002-01)

<http://www.pmra-arla.gc.ca/english/pdf/spn/spn2002-01-e.pdf>

A Decision Framework for Risk Assessment and Risk Management in the Pest Management Regulatory Agency (SPN2000-01)

<http://www.pmra-arla.gc.ca/english/pdf/spn/spn2000-01-e.pdf>





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